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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED THERAPEUTICS CORPORATION	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.:
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT AND JURY DEMAND

Plaintiff United Therapeutics Corporation ("UTC"), by its undersigned attorneys, for its Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.*, involving United States Patent Nos. 6,765,117 ("the '117 patent") (attached as Exhibit A hereto), 8,497,393 ("the '393 patent") (attached as Exhibit B hereto), 7,999,007 (the '007 patent") (attached as Exhibit C hereto), 8,653,137 ("the '137 patent") (attached as Exhibit D hereto), and 8,658,694 ("the '694 patent")(attached as Exhibit E hereto).

2. This action arises out of Teva's submission of Abbreviated New Drug Application ("ANDA") No. 206648 to the United States Food and Drug Administration (the "FDA") seeking approval, prior to the expiration of the '117, '393,'007, '137, and '694 patents, to manufacture, market, and sell a generic copy of UTC's REMODULIN® (Treprostinil Sodium) Injection product which is approved by the FDA for treatment of pulmonary arterial hypertension.

THE PARTIES

3. UTC is a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 1040 Spring Street, Silver Spring, Maryland 20910. UTC is a biotech company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions.

4. Upon information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

7. Upon information and belief, this Court has personal jurisdiction over Teva with respect to this Complaint because, *inter alia*, of its continuous and systematic contacts with this judicial district. Upon information and belief, Teva derives substantial revenue from articles used and consumed in this judicial district and, consistent with its practice with respect to other generic products, following any FDA approval of Teva's ANDA, Teva will sell its generic product throughout the United States, including in New Jersey. Upon information and belief, Teva employs people throughout New Jersey, including at least the following locations: 2 University Plaza Dr, Hackensack, NJ 07601; and 8 Gloria Ln, Fairfield, NJ 07004; and 400 Chestnut Ridge Rd, Woodcliff Lake, NJ 07677. In addition, Teva has previously availed itself of this Court as a forum in which to bring patent litigation against others. *See, e.g., Teva v. Ranbaxy Laboratories Ltd, et al.*, Civil Action No. 3:07-cv-02892-GEB-JJH (D.N.J.).

BACKGROUND

8. UTC holds an approved New Drug Application (No. 21-272) for Treprostinil Sodium Injection, which UTC markets and sells under the registered trademark REMODULIN®.

9. REMODULIN® is a pharmaceutical product initially approved by FDA in the United States in May 2002, and is indicated for the treatment of pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare disease affecting the pulmonary vasculature and resulting in high pressure in the pulmonary arteries and decreased blood flow from the heart to the lungs, thereby depriving the body of oxygen.

10. REMODULIN® is an injectable product approved for sale in 1 mg/mL, 2.5 mg/mL, 5 mg/mL, and 10 mg/mL concentrations.

11. The ’117 patent, entitled “Process for stereoselective synthesis of prostacyclin derivatives,” was duly and legally issued by the United States Patent and Trademark Office on July 20, 2004, and is scheduled to expire on October 24, 2017. The named inventors are Robert M. Moriarty, Raju Penmasta, Liang Guo, Munagala S. Rao, and James P. Staszewski.

12. UTC is the lawful owner of the ’117 patent by assignment of all right, title and interest in and to the ’117 patent, including the right to bring infringement suits thereon.

13. The ’393 patent, entitled “Process to Prepare Treprostinil, the Active Ingredient in Remodulin®,” was duly and legally issued by the United States Patent and Trademark Office on July 30, 2014, and is scheduled to expire December 15, 2028. The named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh.

14. UTC is the lawful owner of the ’393 patent by assignment of all right, title and interest in and to the ’393 patent, including the right to bring infringement suits thereon.

15. The ’007 patent, entitled “Buffer solutions having selective bactericidal activity against gram negative bacteria and methods of using same,” was duly and legally issued by the United States Patent and Trademark Office on August 16, 2011, and is scheduled to expire on March 20, 2029. The named inventors are Roger Jeffs and David Zaccardelli.

16. UTC is the lawful owner of the ’007 patent by assignment of all right, title and interest in and to the ’007 patent, including the right to bring infringement suits thereon.

17. The ’137 patent, entitled “Buffer solutions having selective bactericidal activity against gram negative bacteria and methods of using same,” was duly and legally issued by the

United States Patent and Trademark Office on February 18, 2014, and is scheduled to expire on September 5, 2028. The named inventors are Roger Jeffs and David Zaccardelli.

18. UTC is the lawful owner of the ’137 patent by assignment of all right, title and interest in and to the ’137 patent, including the right to bring infringement suits thereon.

19. The ’694 patent, entitled “Buffer solutions having selective bactericidal activity against gram negative bacteria and methods of using same,” was duly and legally issued by the United States Patent and Trademark Office on February 25, 2014, and is scheduled to expire on September 5, 2028. The named inventors are Roger Jeffs and David Zaccardelli.

20. UTC is the lawful owner of the ’694 patent by assignment of all right, title and interest in and to the ’694 patent, including the right to bring infringement suits thereon.

21. REMODULIN® and its FDA approved manufacture and uses are covered by one or more claims of the ’117 patent, the ’393 patent, the ’007 patent, the ’137 patent, and the ’694 patent, which have been listed in connection with REMODULIN® in the FDA’s *Approved Drug Products with Therapeutic Equivalents* publication (also known as the “Orange Book”).

ACTS GIVING RISE TO THIS ACTION

22. Teva notified UTC on by letter dated July 17, 2014, which was received by UTC on July 21, 2014, (“Teva’s Notice Letter”) that it had filed ANDA No. 206648 with the FDA seeking approval to commercially manufacture, market, use, and sell generic copies of REMODULIN® (Treprostinil Sodium) Injection, 20 mg/20 mL (1 mg/mL), 50 mg/20 mL (2.5 mg/mL), 100 mg/20 mL (5 mg/mL), and 200mg/20mL (10mg/mL) (“Teva’s ANDA Products”) prior to the expiration of the ’117,’393,’007, ’137, and ’694 patents.

23. Teva’s Notice Letter was accompanied by a statement that Teva represented included its basis for believing the ’117 and ’393 patents to be “invalid and/or not infringed.” Yet

that statement did not include any explanation as to why any claim of either the '117 and '393 patents was invalid. The statement also did not include anything beyond conclusory statements regarding alleged non-infringement.

24. Upon information and belief, Teva submitted ANDA No. 203649 with the FDA seeking approval to commercially manufacture, market, use, and sell generic copies of REMODULIN® (Treprostinil Sodium) Injection, 20 mg/20 mL (1 mg/mL), 50 mg/20 mL (2.5 mg/mL), 100 mg/20 mL (5 mg/mL), and 200mg/20mL (10mg/mL) ("Teva's ANDA Products") prior to the expiration of the '117, '393,'007, '137, and '694 patents.

25. Teva's Notice Letter was accompanied by an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

26. Upon information and belief, Teva submitted ANDA No. 206648 to obtain FDA approval to engage in the commercial manufacture, use, and sale of Teva's ANDA Products prior to the expiration of the '117, '393,'007, '137, and '694 patents.

27. Teva's Notice Letter included a statement pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) purporting to recite Teva's "factual and legal bases" for its opinion that the '117 and '393 patents are not valid and/or would not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Products.

28. UTC is commencing this action before the expiration of forty-five days from the date UTC received Teva's Notice Letter.

29. Upon information and belief, Teva's ANDA Products contains the same active compound as UTC's approved REMODULIN® product.

30. Upon information and belief, Teva's ANDA No. 206648 seeks approval from the FDA to market Teva's ANDA Products for the same indication as UTC's approved REMODULIN® product.

31. Upon information and belief, Teva represented to the FDA in ANDA No. 206648 that Teva's ANDA Products is bioequivalent to UTC's approved REMODULIN® product.

32. Upon information and belief, Teva intends to commercially manufacture, sell, offer for sale, and/or import Teva's ANDA Products upon, or in anticipation of, FDA approval.

33. According to Teva's Notice Letter, Teva's ANDA No. 206648 contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) stating that in Teva's opinion the '117 and '393 patents are invalid and/or would not be infringed by the manufacture, use or sale of Teva's ANDA Products.

34. Teva's Notice Letter did not expressly address the '007 patent, the '137 patent, and the '694 patent.

35. When counsel for UTC inquired as to why Teva's Notice Letter did not address the '007 patent, Teva responded that it believed that it had submitted a statement under 21 U.S.C. § 355(j)(2)(A)(viii) for the '007 patent ("Section viii carve out"). A Section viii carve out is essentially a representation to the FDA that approval is sought for a use other than a patented use. *See* 21 U.S.C. § 355(j)(2)(A)(viii).

36. A Section viii carve out cannot be used to address an Orange Book-listed patent containing composition claims. An ANDA applicant must submit either a Paragraph IV or Paragraph III certification for a patent with composition claims.

37. The '007 patent includes composition claims.

38. Upon information and belief, Teva's ANDA contained a Section viii carve out with respect to the '007 patent, the '137 patent, and the '694 patent.

39. Upon information and belief, Teva was aware of the '117, '393,'007, '137, and '694 patents when Teva filed ANDA No. 206648 containing the Paragraph IV certification and Section viii carve out.

40. Upon information and belief, as of the date of Teva's Notice Letter, Teva was aware of the statutory provisions and regulations set forth in 21 U.S.C. §§ 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

COUNT 1 INFRINGEMENT OF THE '117 PATENT UNDER 35 U.S.C. § 271(e)

41. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

42. Upon information and belief, Teva's ANDA Products or an intermediate in its manufacture is covered by one or more claims of the '117 patent.

43. Teva had knowledge of the '117 patent when it submitted ANDA No. 206648.

44. Teva's submission of ANDA No. 206648 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Teva's ANDA Products was an act of infringement of the '117 patent under 35 U.S.C. § 271(e)(2).

45. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA Products would infringe one or more claims of the '117 patent.

46. Upon information and belief, Teva was and is aware of the existence of the '117 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '117 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

47. UTC will be substantially and irreparably damaged and harmed if Teva's infringement of the '117 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 2: INFRINGEMENT OF THE '117 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) and (g)

48. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

49. Upon information and belief, upon FDA approval Teva will manufacture, market, sell, offer to sell, import, and distribute Teva's ANDA Products which will result in infringement of one or more claims of the '117 patent.

50. Teva's ANDA and Teva's intention to engage in the commercial manufacture, use, offer for sale, sale, or importation of Teva's ANDA Products upon receiving FDA approval prior to the expiration of the '117 patent creates an actual and justiciable controversy with respect to infringement of the '117 patent.

51. Upon information and belief, upon FDA approval of Teva's ANDA, Teva's commercial manufacture, use, sale offer for sale and/or importation into the United States of Teva's ANDA Products will directly infringe one or more claims of the '117 patent, and will indirectly infringe by actively inducing infringement by others, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c) and/or 35 U.S.C. § 271(g).

52. Upon information and belief, Teva's ANDA Products or an intermediate in its manufacture as described in and/or directed by Teva's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Teva's ANDA Products would infringe one or more claims of the '117 patent.

53. Upon information and belief, Teva will induce others to infringe one or more claims of the '117 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to the manufacturer of Teva's ANDA Products, or its Active Pharmaceutical Ingredient ("API"), or other subsequent purchasers, distributors, or users thereof, which product or its manufacture constitutes direct infringement of one or more claims of the '117 patent. Upon information and belief, Teva's aiding and abetting includes Teva's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to Teva's ANDA.

54. Upon information and belief, Teva will also contributorily infringe one or more claims of the '117 patent under 35 U.S.C. § 271(c) in that Teva will make, use, sell, offer to sell, and/or import its ANDA Products and/or the API thereof, which Teva knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '117 patent.

55. Upon information and belief, Teva will also infringe one or more claims of the '117 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell or using Teva's ANDA Products or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

56. Upon information and belief, Teva was and is aware of the existence of the '117 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '117 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

57. UTC will be substantially and irreparably damaged and harmed if Teva's infringement of the '117 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 3: INFRINGEMENT OF THE '393 PATENT UNDER 35 U.S.C. § 271(e)

58. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

59. Upon information and belief, Teva's ANDA Products or an intermediate in its manufacture is covered by one or more claims of the '393 patent.

60. Teva had knowledge of the '393 patent when it submitted ANDA No. 206648.

61. Teva's submission of ANDA No. 206648 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Teva's ANDA Products was an act of infringement of the '393 patent under 35 U.S.C. § 271(e)(2).

62. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA Products would infringe one or more claims of the '393 patent.

63. Upon information and belief, Teva was and is aware of the existence of the '393 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '393 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

64. UTC will be substantially and irreparably damaged and harmed if Teva's infringement of the '393 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 4: INFRINGEMENT OF THE '393 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) and (g)

65. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

66. Upon information and belief, upon FDA approval Teva will manufacture, market, sell, offer to sell, import, and distribute Teva's ANDA Products which will result in infringement of one or more claims of the '393 patent.

67. Teva's ANDA and Teva's intention to engage in the commercial manufacture, use, offer for sale, sale, or importation of Teva's ANDA Products upon receiving FDA approval prior to the expiration of the '393 patent creates an actual and justiciable controversy with respect to infringement of the '393 patent.

68. Upon information and belief, upon FDA approval of Teva's ANDA, Teva's commercial manufacture, use, sale offer for sale and/or importation into the United States of Teva's ANDA Products will directly infringe one or more claims of the '393 patent, and will indirectly infringe by actively inducing infringement by others, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c) and/or 35 U.S.C. § 271(g).

69. Upon information and belief, Teva's ANDA Products or an intermediate in its manufacture as described in and/or directed by Teva's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Teva's ANDA Products would infringe one or more claims of the '393 patent.

70. Upon information and belief, Teva will induce others to infringe one or more claims of the '393 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to the manufacturer

of Teva's ANDA Products, or its Active Pharmaceutical Ingredient ("API"), or other subsequent purchasers, distributors, or users thereof, which product or its manufacture constitutes direct infringement of one or more claims of the '393 patent. Upon information and belief, Teva's aiding and abetting includes Teva's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to Teva's ANDA.

71. Upon information and belief, Teva will also contributorily infringe one or more claims of the '393 patent under 35 U.S.C. § 271(c) in that Teva will make, use, sell, offer to sell, and/or import its ANDA Products and/or the API thereof, which Teva knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '393 patent.

72. Upon information and belief, Teva will also infringe one or more claims of the '393 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell or using Teva's ANDA Products or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

73. Upon information and belief, Teva was and is aware of the existence of the '393 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '393 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

74. UTC will be substantially and irreparably damaged and harmed if Teva's infringement of the '393 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 5: INFRINGEMENT OF THE '007 PATENT UNDER 35 U.S.C. § 271(e)

75. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

76. Upon information and belief, use of Teva's ANDA Products is covered by one or more claims of the '007 patent.

77. Teva had knowledge of the '007 patent when it submitted ANDA No. 206648.

78. Teva's submission of ANDA No. 206648 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Teva's ANDA Products was an act of infringement of the '007 patent under 35 U.S.C. § 271(e)(2).

79. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA Products would directly or indirectly infringe one or more claims of the '007 patent.

80. Upon information and belief, Teva will induce others to infringe one or more claims of the '007 patent by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to patients or health care providers that administer Teva's ANDA Product in diluted form for intravenous administration, which use constitutes direct infringement of one or more claims of the '007 patent. Upon information and belief, Teva's aiding and abetting includes Teva's active steps to promote its ANDA Product for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, proposed product package insert labeling pursuant to Teva's ANDA.

81. Upon information and belief, Teva was and is aware of the existence of the '007 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '007 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

82. UTC will be substantially and irreparably damaged and harmed if Teva's infringement of the '007 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 6: INFRINGEMENT OF THE '007 PATENT UNDER 35 U.S.C. §§ 271(a) and (b)

83. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

84. Upon information and belief, upon FDA approval Teva will manufacture, market, sell, offer to sell, import, and distribute Teva's ANDA Products which will result in infringement of one or more claims of the '007 patent.

85. Teva's ANDA and Teva's intention to engage in the commercial manufacture, use, offer for sale, sale, or importation of Teva's ANDA Products upon receiving FDA approval prior to the expiration of the '007 patent creates an actual and justiciable controversy with respect to infringement of the '007 patent.

86. Upon information and belief, Teva will also induce others to infringe one or more claims of the '007 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to patients or health care providers that administer Teva's ANDA Product for the treatment of pulmonary arterial hypertension, which use constitutes direct infringement of one or more claims of the '007 patent. Upon information and belief, Teva's aiding and abetting includes Teva's active steps to promote its ANDA Product for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, its proposed product package insert labeling pursuant to Teva's ANDA.

87. Upon information and belief, the use of Teva's ANDA Product as described in and/or directed by Teva's proposed labeling, ANDA, and/or other corporate documents for Teva's ANDA Product would directly infringe one or more claims of the '007 patent.

88. Upon information and belief, upon FDA approval of Teva's ANDA, Teva's commercial manufacture, use, sale offer for sale and/or importation into the United States of Teva's ANDA Product will infringe one or more claims of the '007 patent, and by actively inducing infringement by others, under 35 U.S.C. § 271(a) and/or 35 U.S.C. § 271(b).

89. Upon information and belief, Teva was and is aware of the existence of the '007 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '007 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

90. UTC will be substantially and irreparably damaged and harmed if Teva's infringement of the '007 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 7: INFRINGEMENT OF THE '137 PATENT UNDER 35 U.S.C. § 271(e)

91. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

92. Upon information and belief, use of Teva's ANDA Products is covered by one or more claims of the '137 patent.

93. Teva had knowledge of the '137 patent when it submitted ANDA No. 206648.

94. Teva's submission of ANDA No. 206648 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Teva's ANDA Products was an act of infringement of the '137 patent under 35 U.S.C. § 271(e)(2).

95. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA Products would directly or indirectly infringe one or more claims of the '137 patent.

96. Upon information and belief, Teva will induce others to infringe one or more claims of the '137 patent by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to patients or health care providers that administer Teva's ANDA Product in diluted form for intravenous administration, which use constitutes direct infringement of one or more claims of the '137 patent. Upon information and belief, Teva's aiding and abetting includes Teva's active steps to promote its ANDA Product for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, proposed product package insert labeling pursuant to Teva's ANDA.

97. Upon information and belief, Teva was and is aware of the existence of the '137 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '137 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

98. UTC will be substantially and irreparably damaged and harmed if Teva's infringement of the '137 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 8: INFRINGEMENT OF THE '137 PATENT UNDER 35 U.S.C. §§ 271(a) and (b)

99. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

100. Upon information and belief, upon FDA approval Teva will manufacture, market, sell, offer to sell, import, and distribute Teva's ANDA Products which will result in infringement of one or more claims of the '137 patent.

101. Teva's ANDA and Teva's intention to engage in the commercial manufacture, use, offer for sale, sale, or importation of Teva's ANDA Products upon receiving FDA approval prior to the expiration of the '137 patent creates an actual and justiciable controversy with respect to infringement of the '137 patent.

102. Upon information and belief, Teva will also induce others to infringe one or more claims of the '137 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to patients or health care providers that administer Teva's ANDA Product for the treatment of pulmonary arterial hypertension, which use constitutes direct infringement of one or more claims of the '137 patent. Upon information and belief, Teva's aiding and abetting includes Teva's active steps to promote its ANDA Product for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, its proposed product package insert labeling pursuant to Teva's ANDA.

103. Upon information and belief, the use of Teva's ANDA Product as described in and/or directed by Teva's proposed labeling, ANDA, and/or other corporate documents for Teva's ANDA Product would directly infringe one or more claims of the '137 patent.

104. Upon information and belief, upon FDA approval of Teva's ANDA, Teva's commercial manufacture, use, sale offer for sale and/or importation into the United States of Teva's ANDA Product will infringe one or more claims of the '137 patent, and by actively inducing infringement by others, under 35 U.S.C. § 271(a) and/or 35 U.S.C. § 271(b).

105. Upon information and belief, Teva was and is aware of the existence of the '137 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '137 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

106. UTC will be substantially and irreparably damaged and harmed if Teva's infringement of the '137 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 9: INFRINGEMENT OF THE '694 PATENT UNDER 35 U.S.C. § 271(e)

107. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

108. Upon information and belief, use of Teva's ANDA Products is covered by one or more claims of the '694 patent.

109. Teva had knowledge of the '694 patent when it submitted ANDA No. 206648.

110. Teva's submission of ANDA No. 206648 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Teva's ANDA Products was an act of infringement of the '694 patent under 35 U.S.C. § 271(e)(2).

111. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA Products would directly or indirectly infringe one or more claims of the '694 patent.

112. Upon information and belief, Teva will induce others to infringe one or more claims of the '694 patent by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to patients or health care providers that administer Teva's ANDA Product in diluted form for intravenous administration, which use constitutes direct infringement of one or more claims of the '694 patent. Upon information and belief, Teva's aiding and abetting includes Teva's active steps to promote its ANDA Product for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, proposed product package insert labeling pursuant to Teva's ANDA.

113. Upon information and belief, Teva was and is aware of the existence of the '694 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '694 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

114. UTC will be substantially and irreparably damaged and harmed if Teva's infringement of the '694 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 10: INFRINGEMENT OF THE '694 PATENT UNDER 35 U.S.C. §§ 271(a) and (b)

115. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

116. Upon information and belief, upon FDA approval Teva will manufacture, market, sell, offer to sell, import, and distribute Teva's ANDA Products which will result in infringement of one or more claims of the '694 patent.

117. Teva's ANDA and Teva's intention to engage in the commercial manufacture, use, offer for sale, sale, or importation of Teva's ANDA Products upon receiving FDA approval prior to the expiration of the '694 patent creates an actual and justiciable controversy with respect to infringement of the '694 patent.

118. Upon information and belief, Teva will also induce others to infringe one or more claims of the '694 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to patients or health care providers that administer Teva's ANDA Product for the treatment of pulmonary arterial hypertension, which use constitutes direct infringement of one or more claims of the '694 patent. Upon information and belief, Teva's aiding and abetting includes Teva's active steps to promote

its ANDA Product for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, its proposed product package insert labeling pursuant to Teva's ANDA.

119. Upon information and belief, the use of Teva's ANDA Product as described in and/or directed by Teva's proposed labeling, ANDA, and/or other corporate documents for Teva's ANDA Product would directly infringe one or more claims of the '694 patent.

120. Upon information and belief, upon FDA approval of Teva's ANDA, Teva's commercial manufacture, use, sale offer for sale and/or importation into the United States of Teva's ANDA Product will infringe one or more claims of the '694 patent, and by actively inducing infringement by others, under 35 U.S.C. § 271(a) and/or 35 U.S.C. § 271(b).

121. Upon information and belief, Teva was and is aware of the existence of the '694 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '694 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

122. UTC will be substantially and irreparably damaged and harmed if Teva's infringement of the '694 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, UTC requests the following relief:

1. A judgment that Teva:

   A. has infringed the '117 patent, the '393 patent, the '007 patent, the '137 patent, and/or the '694 patent;

B. will induce infringement of the ’117 patent the ’393 patent, the ’007 patent, the ’137 patent, and/or the ’694 patent, and

C. will contribute to the infringement by others of the ’117 patent and/or the ’393 patent;

2. A judgment ordering that the effective date of any FDA approval for Teva to commercially manufacture, make, use, offer to sell, sell, market, or import into the United States Teva’s ANDA Products be not earlier than the latest of the expiration dates of the ’117 patent the ’393 patent, the ’007 patent, the ’137 patent, and/or the ’694 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which UTC is or may become entitled;

3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Teva, its officer, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation, or privity with them, their successors, and assigns, from infringing, contributorily infringing, or inducing others to infringe the ’117 patent the ’393 patent, the ’007 patent, the ’137 patent, and/or the ’694 patent, including engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 206648 and/or any applicable DMF until the expiration of the ’117 patent the ’393 patent, the ’007 patent, the ’137 patent, and/or the ’694 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which UTC is or may become entitled;

4. A judgment declaring that making, using, selling, offering for sale, or importing into the United States of Teva’s ANDA Products, or any product or compound that infringes one or more of the ’117 patent the ’393 patent, and the ’007 patent, prior to the expiration dates of the respective patents, will infringe, actively induce infringement of, and will contribute to the

infringement by others of the '117 patent the '393 patent,'007 patent, the '137 patent, and/or the '694 patent;

5. Temporary, preliminary, permanent, or other injunctive relief as necessary or appropriate should Teva seek to commercially manufacture, use, sell, offer to sell, or import Teva's ANDA Products prior to disposition of this action and/or the expiration of the '117 patent the '393 patent, the '007 patent, the '137 patent, and/or the '694 patent;

6. A judgment awarding UTC damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(c) and 284, if Teva commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 206648 that infringes one or more of the '117 patent the '393 patent, the '007 patent, the '137 patent, and/or the '694 patent;

7. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding UTC its attorney's fees;

8. Costs and expenses in this action; and

9. Such further and other relief as this Court may deem just and proper.

JURY DEMAND

UTC requests trial by jury for any issues so triable.

Respectfully submitted,

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Dated: September 2, 2014

Attorneys for Plaintiff
United Therapeutics Corporation

LOCAL CIVIL RULE 11.2 CERTIFICATION

UTC hereby certifies that, to its knowledge, the matter in controversy in this action is not the subject of any other pending lawsuit, arbitration, or administrative proceeding other than the following identified proceedings:

- *United Therapeutics Corporation v. Sandoz, Inc.* (3:12-cv-01617-PGS-LHG) (D.N.J.);
- *United Therapeutics Corporation v. Sandoz, Inc. et al.* (3:13-cv-00316-PGS-LHG) (D.N.J.).

Respectfully submitted,

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